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10/587,524

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Goran Bijelic

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EXAMINER

PORTER, JR, GARY A

ART UNIT

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3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/587,524 | Applicant(s) BIJELIC ET AL. | |
| | Examiner GARY A. PORTER, JR | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 8-11 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Minogue et al. (WO 2004/098703).

3. Regarding Claims 1 and 9, Minogue teaches a muscle stimulation apparatus comprising a flexible substrate, i.e. garment 12 and overgarment with inner surface 50 and outer surface 52 (Fig. 1-3), that contains a plurality of stimulation electrodes fastened thereon (page 11, lines 1-19). Furthermore, Minogue teaches a stimulation controller 58 that selectively activates specific stimulation electrodes based on a combination of software programming and user operable controls (page 12, lines 21-30). Lastly, Minogue teaches securing the array of electrodes to the skin by way of hook-and-loop fasteners 42 present on the flexible substrate (page 11, lines 10-13).

4. With regards to Claim 8, Minogue teaches the controller 58 has means for selectively activating and controlling each electrode, therefore incorporating the

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switching means within the controller. Minogue further teaches that the controller 58 is carried by the outergarment portion of the flexible substrate (Fig. 3).

5. In regards to Claim 10, Minogue teaches that the controller 58 contains an electronic user interface, i.e. LCD screen, that allows a user to interact via a button control panel that selectively activates medial and lateral muscle stimulation (page 12, lines 21-30) and to choose the desired current pathways through the thigh (page 17, lines 14-22). This controller inherently possesses the switching unit since the controller activates and deactivates certain electrodes based on user input.

6. Regarding Claim 11, Minogue teaches reprogramming the controls to accommodate the change in stimulation site in order to stimulate desired user muscle movement (page 12, line 21-page 13, line 5).

7. In regards to Claim 13, the Examiner notes that the term “electrode array” defines a plurality of electrodes. Therefore, with respect to Minogue, two electrodes could be considered an electrode array (for instance electrodes A and B). Therefore, electrodes C and D could be considered, given the broadest reasonable interpretation of the claim language, one or more electrodes connected to said switch means since the electrodes are electrically connected to controller 58 (Fig. 4,5; page 13, lines 7-18).

8. Regarding Claim 14, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or

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functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Specifically in regards to the structure of Claim 14, Minogue teaches a muscle stimulation system that has a controller 58 that allows a user to specifically set an electrode or group of electrodes to either be a cathode or an anode (page 17, lines 14-22). Additionally, although Minogue teaches that combining the electrodes to be anodes and cathodes reduces skin sensation and current density, Minogue does disclose implicitly that the electrodes also have the ability to be selectively turned on and off (e.g. Minogue states that the combined electrodes provide a more subtle sensation than using an individual electrode) (page 18, lines 7-32). Therefore, although Minogue does not disclose the exact functional step of activating at least two electrodes and deactivating a third electrode, Minogue has demonstrated the capability of performing such a step, thus anticipating the claim.

9. In regards to Claim 15, Minogue teaches the stimulation system contains stimulator electronics (page 12, lines 21-23).

10. Regarding Claim 16, Minogue teaches a stimulation apparatus comprising a flexible substrate, i.e. garment 12 and overgarment with inner surface 50 and outer surface 52 (Fig. 1-3), that contains a plurality of stimulation electrodes fastened thereon (page 11, lines 1-19). Furthermore, Minogue teaches a stimulation controller 58 that selectively activates specific stimulation electrodes based on a combination of software programming and user operable controls (page 12, lines 21-30). Lastly, Minogue

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teaches securing the array of electrodes to the skin by way of hook-and-loop fasteners 42 present on the flexible substrate (page 11, lines 10-13).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byers et al. (4,969,468) in view of Utely et al. (6,277,116), further in view of Thompson (6,690,959).

14. Regarding Claims 1 and 12, Byers discloses an electrode array for stimulating tissue comprising an electrode array (Fig. 1) with a flexible base (col. 10, lines 21-24)

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for placement on the skin of a patient (col. 4, lines 25-27). Byers also discloses an external controller that provides control over a switching network, i.e. a multiplexer 36, via a wireless communication link, wherein the controller selectively activates particular electrode needles to activate(col. 8, lines 1-31). Byers does not disclose in detail whether the control signals are generated manually or automatically nor does Byers disclose how the electrode array is secured to the skin. However, Utely teaches, as is well known in the art, that controllers remote from the stimulation electrode array can be used by a physician to manipulate stimulation parameters in order to focus application of stimulation energy in selected patterns (col. 6, line 59-col. 7, line 3).

Additionally, Thompson teaches that it is common to apply adhesive to skin-mounted electrodes in order to secure the electrode to the desired tissue area (col. 2, lines 14-17; col. 6, lines 22-36). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Byers reference to include a user operable controller for selectively controlling stimulation electrodes, as taught and suggested by Utely, and to include an adhesive layer on the skin contacting portion of the array, as taught and suggested by Thompson, for the purpose of focusing stimulation into selected patterns and of securing the electrode array to the desired stimulation site.

15. In regards to Claim 2, Byers teaches arranging the electrodes into rows and columns (col. 10, lines 35-36).

16. With regards to Claim 3, Byers discloses a particular embodiment wherein the array contains sixteen needle electrodes 2 (Fig. 2).

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17. Regarding Claim 4, Byers does not disclose a specific lower bound of electrodes. However, Byers does disclose implicitly that the array can contain as many electrodes as are necessary to cover a desired area. Specifically, Fig. 1 portrays approximately 25 electrodes (although not explicitly mentioned in the specification) and Fig. 2 portrays 16 electrodes in the array. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include at least 24 electrodes instead of 16 (as exemplified in Fig. 2 of Byers), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

18. In regards to Claim 5, Byers teaches providing equidistant spacing between adjacent electrodes (col. 10, lines 40-42).

19. Regarding Claims 6 and 7, Byers discloses that the spacing between adjacent electrodes is a function of the desired electrode density. In a preferred embodiment, Byers discloses that the spacing is ideally between 0.5 microns to 100 microns (col. 9, lines 31-33).

Response to Arguments

20. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

21. Minogue et al. (WO 2004/098703) and newly found references Byers et al. (4,969,468), Utely et al. (6,277,116) and Thompson (6,690,959) have been applied in response to Applicant's amendment to Claim 1.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 7AM - 4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766